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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/513,997

02/15/00

HARRINGTON

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5817-70

SEANKS AND HELPER  
TRANSFOTOMAC PLAZA  
1133 N. FAIRFAX ST.,  
SUITE 305  
ALEXANDRIA VA 22314

AN12/0823

EXAMINER

BRUNOVSKIS, P

ART UNIT

PAPER NUMBER

1632

DATE MAILED:

08/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/513,997

Applicant(s)

HARRINGTON ET AL.

Examiner

Peter Brunovskis

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 83-88,92,100-103,106 and 107 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 83-88,92,100-103,106 and 107 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

The response filed 6/14/01 (Paper No. 12) has been entered. Amendment of claims 83, 88, 92, 100-102, cancellation of claims 58-82, 89-91, 93-99, 104, 105 and entry of new claims 106 and 107 is acknowledged.

Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn. Unless otherwise indicated, arguments directed to rejections rendered moot by Applicants amendments or Examiner's withdrawal will not be further addressed or acknowledged. Claims 83-88, 92, 100-103, 106, and 107 are pending in the instant application.

### ***Information Disclosure Statement***

In response to the Examiner's request for copies and/or English translations of references AC2, AN2 and AO2, Applicants claim to have provided copies of such documents, including an English abstract for AO2 (i.e. AT24), which was said to have been submitted in the first IDS filed with this application (i.e. 2/26/00). However, no such copies have been provided as indicated, nor could the English abstract for AO2 (AT24) be found in the first IDS as asserted. Thus, AC2, AN2, and AO2 could not be considered.

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*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 83-88, 92, 100-103, 106, and 107 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 106 and 107 (and dependent claims) are indefinite in their recitation of "portion thereof" since it is unclear what this term is directed to or what metes and bounds apply to this term in the context of over-expressing a protein encoded by said "portion", since "portion[s]" do genes don't ordinarily encode proteins. Further, step (c) does not clearly relate back to the preamble which recites a "method for over-expressing protein encoded by an endogenous cellular gene *or portion thereof*" (emphasis added). Step (c) recites "said over-expression being the result of upregulation of said gene" and "over-expressing said protein encoded by said endogenous cellular gene" without reference to "portion thereof".

Claim 107 is indefinite in its recitation of step (d) which does not sufficiently convey the meaning and scope of the term "detecting" using appropriate active process steps (i.e. detect how?).

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 107 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Newly entered claim 107 is drawn to a method for detecting over-expression of an endogenous cellular gene in a cell introduced into an animal. There is no evidence of support for such a method as claimed.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.

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MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure*" (emphasis added).

Claims 83-88, 92, and 100-103 remain rejected and claims 106, and 107 are rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the Office Action of 2/14/01 as previously applied to claims 81, 83-88, 92, and 100-103, and for the reasons set forth below, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Newly entered claim 106 is essentially drawn to the same scope of subject matter as previously examined claim 81 and is rejected for the reasons of record. Newly entered claim 107 is drawn to a method of detecting over-expression of a protein from a cell introduced into an animal and is not enabled because the specification provides no guidance for practicing this detection process as claimed. For example, the claimed method reads on introduction of single cells into an animal, yet the specification fails to teach how to provide any guidance concerning for any methodology to detect such overexpression, or how to process the requisite samples for testing, particularly when detecting over-expression from a single cell introduced into e.g. a

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complex multicellular organism. Such a process would clearly require undue experimentation employing unspecified methodologies not disclosed in the instant specification.

Applicant's arguments filed 6/14/01 and signed declaration filed 7/12/01 have been fully considered but they are not persuasive. The response argues that "the rationale for the rejection appears to be that the invention lacks utility because cell therapy is an inoperable embodiment and no other useful embodiments are asserted" (paragraph abridging p. 12-13). This argument and others relating to such as set forth on p. 12-20 are not germane to the instant case, since no utility rejection was made. The relevant question is whether the specification provides an enabling disclosure under the "how to make and use" clause of 35 USC 112, first paragraph for the claimed subject matter.

The claims are broadly drawn to methods for over-expressing protein encoded by endogenous genes or portions thereof *in vivo*. The claims are considered in light of the specification, wherein the only readily apparent use disclosed is for cell therapy which is not enabled for the reasons of record, the grounds of which have not been disputed by Applicants. There is no other specifically disclosed use for the methods. Inasmuch as the claimed methods read on cell therapy, which has a well-established utility, no utility rejection was made. Applicants have argued that a process of non-therapeutic *in vivo* protein production constitutes a specific, credible, substantial, and well-established utility. Thus, the response includes a declaration under 37 C.F.R. 1.132 by co-inventor John J. Harrington, filed 7/12/01 that non-therapeutic-based *in vivo* expression as claimed in the instant application has a specific, substantial, credible, or well-

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established utility (p. 12-20 of response) and that the claimed methods have a practical, real-world use (see e.g. declaration, p. 2, point 3).

Applicants arguments and declaratory evidence are not persuasive for the following reasons. First, the claims do not recite any limitations that limit the claimed subject matter to non-therapeutic protein expression or that exclude therapeutic cell therapy (particularly when read in light of the specification). Secondly, despite reference to cell-based protein production, isolation and purification, no such steps are recited in the claimed methods. Further there is no evidence of record to support Applicants assertion that "the specification also discloses the isolation and purification of protein produced in an animal by the cells of the invention" as stated in point 5 of the declaration. Further, there is no evidence of record that such a process for producing and/or purifying proteins from animals was routinely performed in the art using the methodology of the claimed invention.

The declaration further sets forth arguments concerning various references that were neither supplied, nor listed in a PTO-1449. Therefore these references and the arguments directed to such could not be considered. However, it is noted for the record that the statements on p. 4, point 8 relating to introduction of hybridomas for producing antibodies in animals does not appear to be germane to the case, since the instant application does not does not disclose or provide any nexus for in vivo introduction of hybridomas. Absent evidence to the contrary, there is no evidence to suggest that one skilled in the art would have had any reason to construe the claimed



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disclosure as embracing methods for producing antibodies from hybridomas introduced into animals.

Further, with regard to the disclosures in U.S. 5,641,670 or U.S. 5,733,761, which are of record, Applicants arguments (p. 5-7, point 9) are not persuasive with respect to enablement, because they fail to establish a nexus between the claimed methods of the instant invention and the *claims* deemed to be enabled by the issued patent.

Although arguments directed to unsupplied references could not be addressed with respect to their specifics, it is generally noted for the record, that the alleged disclosures described by co-inventor Harrington appear to be directed to methods with different and distinct purposes, relying on specific products, lacking any clear nexus to the instant application, particularly since none of the products or methodologies disclosed therein appear to be described in the instant application. The specification fails to provide guidance as to how the skilled artisan would use the claimed method for non-therapeutic expression of a protein.

The instant invention, as claimed, falls under the "germ of an idea" concept defined by the CAFC. The court has stated that "patent protection is granted in return for an enabling disclosure, not for vague intimations of general ideas that may or may not be workable". The court continues to say that "tossing out the mere germ of an idea does not constitute an enabling disclosure" and that "the specification, not knowledge in the art, must supply the novel aspects of an invention in order to constitute adequate enablement". (See *Genentech inc v. Novo Nordisk*

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A/S 42 USPQ2d 1001, at 1005). The compositions and methods of the claimed invention constitute such a "germ of an idea".

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 83, 86, 87, 92, 101, and 102 remain rejected and claim 106 is rejected under 35 U.S.C. 102(e) for the reasons of record previously applied to claims 81, 83, 86, 87, 92, and 100-102 as being anticipated by Sands et al. (U.S. 6,136,566, filed 10/4/96), as further evidenced by Vasallo et al. (Bioch. Biophys. Res. Commun., 270(3):1036-1040, 4/00), and for the additional reasons set forth below.

Newly entered claim 106 is essentially drawn to the same scope of subject matter as previously examined claim 81 and is rejected for the reasons of record. The claim newly recites the limitation directed to over-expression of protein encoded by an endogenous cellular gene *or portion thereof* (emphasis added). Sands et al. teaches a method for introducing a non-homologously recombinant cell (e.g. ES cell) in an animal using a vector over-expressing a

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marker protein which reads on a portion of an endogenous cellular gene, since it contains the same amino acids (i.e. portions) that are present in any endogenous cellular protein.

Applicant's arguments filed 6/14/01 have been fully considered but they are not persuasive. The response contends that new claim is limited to producing protein from the endogenous gene in the animal, that Sands neither discloses nor suggests the production of protein from the endogenous gene either in vitro, in the cell introduced into an animal, or in the transgenic animal, and that Sands actually teaches away from translation of the endogenous gene, in either context (last paragraph, p. 22). Applicants further argue that the Sands vectors only provide for the marker RNA to be translated, not the endogenous gene (or portions thereof), that the purpose of producing RNA from the endogenous gene is to provide nucleic acid sequence information about the gene, and that the goal of Sands is to provide a "knock-out" mouse for every gene in the genome and to use the mouse to determine the function of the gene (p. 23, first two paragraphs). To the extent that the claims read on "portions thereof", the vectors of Sands designed to over-express marker proteins anticipate the subject matter as claimed. Deletion of the limitation "or portion thereof" in the preamble would obviate the rejection.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim 107 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sands et al. for the reasons applied to claims 83, 86, 87, 92, 100-102, and 106 above under 35 U.S.C. 102 and for the reasons set forth below (U.S. 6,136,566, filed 10/4/96).

Sands et al. has been described. Claim 107 only differs from the claimed claim 106 to the extent that it additionally recites a step for detecting protein expression (i.e. step d). This step is implicit in any method that involves creation of transgenic animals from ES cells, which involve a detection step to verify that the animal is in fact transgenic with respect to the genotype of the ES cells used to create the transgenic animal. Newly entered claim 107 is drawn to a method of detecting over-expression of a protein from a cell introduced into an animal, which is implicit in the method of by Sands et al. and is therefore prima facie obvious.

Claims 83-85 remain rejected and claim 106 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sands in view of Schmidt et al. (Mol. Cell. Biol. 10(8):4406-4411, 8/90) for the

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reasons set forth in the Office Action of 2/14/01 and for the reasons set forth below in accordance with the response to Applicants arguments directed to the 35 U.S.C. 102 rejection above.

Sands has been described. Applicant's arguments filed 6/14/01 have been fully considered but they are not persuasive, since they are predicated on Sands being an improper reference for the reasons given in response to the rejection under 35 U.S.C. 102. Since Applicants have failed to overcome the basis for this rejection, in accordance with the newly claimed subject matter and the newly directed arguments thereto, and since Applicants have failed to provide specific evidence to negate the *combination* of Sands and Schmidt, they have failed to overcome the prima facie case for obviousness.

Claims 83 and 87 remain rejected and claim 106 is rejected are rejected under 35 U.S.C. 103(a) as being unpatentable over Sands in view of Bujard et al. (U.S. 5,912,411, filed 6/7/95) for the reasons set forth in the Office Action of 2/14/01 and for the reasons set forth below in accordance with the response to Applicants arguments directed to the 35 U.S.C. 102 rejection above.

Sands has been described. Applicant's arguments filed 6/14/01 have been fully considered but they are not persuasive, since they are predicated on Sands being an improper reference for the reasons given in response to the rejection under 35 U.S.C. 102. Since Applicants have failed to overcome the basis for this rejection, in accordance with the newly claimed subject matter and the newly directed arguments thereto, and since Applicants have failed to provide specific

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evidence to negate the *combination* of Sands and Schmidt, they have failed to overcome the prima facie case for obviousness.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 83-88, 100, 102, and 103 remain provisionally rejected and claim 106 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 99-104, 128, 131, and 132, respectively, of copending Application No. 09/276,820. Although the conflicting claims are not identical, they are not patentably distinct from each other because rejected claims 83-88, 100, 102, 103, and 106 are embraced by claims 99-104, 128, 131, and 132 of copending application 09/276,820.

Claims 83-88, 92, and 100-103 remain provisionally rejected and claim 106 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 81, 83-88, 92, and 100-103, respectively, of copending

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Application No. 09/479,122. Although the conflicting claims are not identical, they are not patentably distinct from each other because rejected claims 83-88, 92, 100-103, and 106 are embraced by claims 81, 83-88, 92, and 100-103 of the copending application.

Claim 100 remains provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 88 of copending Application No. 09/481,375; claim 60 of copending Application Nos. 09/455,659 and 09/513,575; and claim 59 of copending Application Nos. 09/479,123 and 09/513,574. Although the conflicting claims are not identical, they are not patentably distinct from each other because rejected claim 100 is embraced by claim 88 of copending application 09/481,375, and because rejected claim 100 embraces the recited claims of copending applications 09/455,659, 09/513,575, 09/479,123, and 09/513,574.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed 6/14/01 traversing the grounds for rejection as applied to provisional obviousness-type double patenting over 09/479,122 have been fully considered but they are not persuasive. The arguments are based on Applicants position that the rejection is alleged to be inconsistent with the Examiner's restriction requirement in the present case (p. 31, last paragraph). The response then goes on to retrospectively question the Examiner's position that the methods of groups V and VI are patentably distinct (based on combination-subcombination reasoning) which is moot. The arguments fail to provide any basis for patentably

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distinguishing the claimed subject matter directed to overexpression of proteins (or portions thereof) from cells introduced in animals ex vivo from the claims in the pending applications directed to overexpression of genes (or portions thereof) from cells introduced in animals ex vivo.

With regard to Applicants interpretation of the Examiner's alleged inconsistency associated with not considering as patentably distinct methods directed to those incorporating additional structural limitations, it is not clear what point Applicants are trying to make or what "additional elements recited above" (p. 33, line 10) refers to. The method of claim 81 in the '122 application comprises a vector containing a transcriptional regulatory sequence; thus the in vivo delivery method of '122 application anticipates the instantly claimed methods which are patentably distinct by combination-subcombination criteria. Applicants will recall that the claimed in vivo delivery methods of the '122 application were only included for examination in the '122 application to the extent that they comprised the use of the same vector compositions in accordance with Applicants election. Thus there is no contradiction or inconsistency. Examination and restriction of the instant application and the '122 application was in accordance with the specific considerations and agreed-upon instructions in each case.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX number is (703) 308-4242 or 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Brunovskis whose telephone number is (703) 305-2471. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda can be reached at (703) 305-6608.

Any inquiry of a general nature or relating to the status of this application should be directed to the Patent Analyst, Patsy Zimmerman whose telephone number is (703) 308-8338.

Peter Brunovskis, Ph.D.  
Patent Examiner  
Art Unit 1632

  
DEBORAH CROUCH  
PRIMARY EXAMINER  
GROUP 1800/1630